Federal Office of Consumer Protection and Food Safety

Timelines in Regulations and Guidance Documents

Member State Germany,

Federal Office of Consumer Protection and Food Safety (BVL)

Timelines in Regulations and Guidance Documents

- **Issue:** Misalignment between current regulatory timelines and increased procedural complexity
- **Scope:** Critical evaluation of procedural steps as the Admissibility Check, the preparation of the DAR/RAR or of the reporting table
- **Objective:** Exploring opportunities to reduce workload and enhance efficiency

Admissibility Check

Experienced issues

- **More complex** due to legal requirements and the dossier submissions via *IUCLID*
- **Amendments of dossiers by applicants** ususally necessary, inducing further checks by RMS
- **Uncertainties** concerning the required **quality of dossiers** to declare admissibility and **depth of validation** (checking formal admissiblility or dossier quality for following risk assessment)

Regulation (EG) Nr. 1107/2009
NAS: *45 days + 3 months applicant*

Implementing Regulation (EU) Nr. 1740/2020 (844/2012)
Renewal: *30 days + 14 days applicant*

Proposal:

Dialogue between EFSA and MSs to develop a best practice and harmonised approach for declaration of admissibility

Preparation of DAR/RAR

Experienced issues

- Generally, **evaluation** became more **extensive and complex** over the past years (e.g. ED and co-formulants assessments, in future: new hazard classes)
- Continuous **adaptations and increase of information** in AR templates and appendices

Proposal:

Dialogue between EFSA and MSs to develop a best practice and harmonised approach

Regulation (EG) Nr. 1107/2009
NAS: *12 months + max. 6 months for applicant*

Implementing Regulation (EU) Nr. 1740/2020 (844/2012) Renewal: *12 months (data request within this time period)*

Vol. 1 > Tables Lines of evidence

- Already included in required ED Excel Sheet (Appendix E)
- Duplicate work with effort for formatting

Possible Solution: Omitting Tables in Vol. 1

General Proposal for Peer Review

Proposal

Dialogue between EFSA and MSs to develop a best practice and harmonised approach

Concerning the commenting phases in the Peer Review

- For a harmonized use of the correct data requirements, guidance documents, data models etc., an integration of **application dates** in call for comments would be helpful.
- To avoid misunderstandings it would be appreciated if the **UUID** was included in the call for comments for additional information (RMS: for confirmatory information)

Reporting Tables/Additional Information

Experienced issues

- Currently, the **compilation** of comments demands time and effort due to media discontinuity
- **High number of studies and information** submitted as additional information

Proposal:

Dialogue between EFSA and MSs to develop a harmonised definition of „need to know“ and „nice to know“ aspects to reduce high information load for RMS

Administrative Guidance on pesticides and MRL: *[...] comments [...] are forwarded to RMS. The applicant is invited by the RMS to react on the comments compiled. Then, the RMS evaluates the comments and the applicant's responses and EFSA concludes on the way forward for each of them [...]. The main actions [...] are agreed in the kick-off teleconference organised between EFSA-(co)-RMS-(ECHA-EC).*

Flowchart: *6 weeks for collecting comments (EFSA), compiling Reporting Table (RMS), commenting (APP) and Kick-off (EFSA/RMS)*

Summary

Issue: Misalignment between current regulatory timelines and increased procedural complexity

Procedural step:	Proposal:
Admissibility	
Preparation of DAR/RAR	Dialogue between EFSA and MSs to explore opportunities for reducing workload and enhancing efficiency
General Proposal for Peer Review	
Reporting Tables/ Additional Information	

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